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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,044	04/21/2004	Robert Falotico	CRD0933CIP	7418

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EXAMINER

NGUYEN, CAMTU TRAN

ART UNIT	PAPER NUMBER
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3772

NOTIFICATION DATE	DELIVERY MODE
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10/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No. 10/829,044	Applicant(s) FALOTICO ET AL.	
	Examiner Camtu T. Nguyen	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 2/7/2008, claims 69-74 are newly added.

Applicant's response to the Objections presented in the previous Office Action is acknowledged, thus, such Objections have been removed.

Applicant's comments directed to prior art of Schwartz et al reference under 102(b) rejection are noted and deemed persuasive, particularly to its lacking the teaching of the amount of rapamycin therapeutic drug.

Upon reconsideration of the claims & carefully study of the prior art, applicant's pending claims deemed not in condition for allowance based on the following interpretation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 60 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Namely, there is no support for “3 µg to 13 µg per millimeter of stent length of rapamycin”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (U.S. Patent No. 6,368,658).

Schwarz et al discloses apparatus and methods for coating medical devices, example of which devices include implantable device such as vascular grafts, stent grafts (column 3 lines 40-55).

Schwarz et al discloses the coating materials including polymeric material (column 2 lines 8-10).

Schwarz et al further discloses that the coating materials used in conjunction with therapeutic drug/agent (column 3 lines 66-67, column 4 lines 1-3 & 15-17) such as rapamycin (column 4 lines 35-37).

With regards to claims 60 reciting the amount of rapamycin coating the stent, such recitation is consistent with applicant's disclosure on page 24 lines 13-16 which supports the stent may be coated with various drug/drug combinations in therapeutic dosage amounts. With regards to claim 60 reciting the specific amount of 3 µg to 13 µg per millimeter of stent length of rapamycin, such specific amount is not unobvious and within the skills of ordinary in the art since the amount of therapeutic drug may be and can be predetermined or measured prior to mixing/incorporating with the polymeric materials such that the recited amount range may be

Art Unit: 3772

easily chosen as one skilled in the art found it suitable to tailor for a particular medical application.

With regards to the wherein statement recited in claims 60-63 and 69-74, such statements are a mere functional recitation and a mere statement of intended use. Furthermore, the scenarios presented in these wherein statement show no unusual, no unobvious, nor any unexpected results and it is therefore deemed to fall within the purview of ordinary lab/engineering practice. Applicant's disclosure lacks a showing of criticality and/or any new unusual or unobvious results from the claimed scenarios.

With regards to claims 64, the Schwarz et al discloses EXAMPLE 4 with a barrier layer is applied to the stents coated with a polymeric/drug layer, the barrier layer is polymeric composition (column 14 lines 23-33).

With regards to claims 65 & 68, the coating of polymeric/drug layer is on the outer surface of the stent. The Schwarz et al stent inherently would perform the method of inhibiting neointimal proliferation in a human coronary artery.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772